CD HORIZON® Spinal System
510(k) Summary
July 8, 2013

I. Company:
Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

AUG 0 6 2013

II. Contact:
Lauren Kamer
Senior Regulatory Affairs Specialist

III. Proprietary Trade Name: CD HORIZON® Spinal System

IV. Common Name: Spinal Fixation Appliance, Spinal Fixation Orthosis

V. Classification Name: Spinal Interlaminal Fixation Orthosis,
Spinal Intervertebral Body Fixation Orthosis,
and Pedicle Screw Spinal System
(21 CFR 888.3050, 888.3060 and 888.3070)

Classification: Class III (Pre-amendment)

Product Codes: NKB, KWP, KWQ, MNH, MNI, and OSH

VI. Product Description

The CD HORIZON® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK® Plates, staples and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

A subset of CD HORIZON® Spinal System components may be used for posterior pedicle screw fixation in pediatric cases. These constructs may be comprised of a variety of shapes and sizes of rods (ranging in diameter from 3.5mm to 6.35mm), hooks, screws,

CROSSLINK® Plates, and connecting components. Similarly to the CD HORIZON® implants used in adult cases, these components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The system also includes various instruments used to assist in the implantation of the system via minimally invasive approaches.

The purpose of this submission is to modify Medtronic's CD HORIZON® Spinal System to add additional lined rods to the system, specifically, 4.75mm lined rods in cobalt-chromium-molybdenum alloy.

VII. Indications for Use

The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD HORIZON® SPIRE™ Plate is a posterior, single level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined); spondylolisthesis; trauma; and/or tumor.

In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.

VIII. Summary of Technological Characteristics

The subject CD HORIZON® Spinal System, including the additional lined rods, has the same fundamental scientific technology as the predicate CD HORIZON® Spinal System. Like the predicate CD HORIZON® Spinal System rods, the subject rods are 4.75mm in diameter and are 500mm in length. The subject rods are manufactured from the same cobalt chromium alloy per ASTM F1537 as the predicate rods. The subject rods are lined to provide a visual aid to the surgeon when contouring the rod in a certain plane

IX. Identification of the Legally Marketed Predicate Devices Used to Claim Substantial Equivalence

The design features, materials, labeling, and indications for use of the subject devices are substantially equivalent to devices previously cleared as part of CD HORIZON® Spinal System (K131321, SE Jun 5, 2013; K091974, SE Sept 2, 2009; K042025, SE Aug 25, 2004).

X. Brief Discussion of the Non-Clinical Tests Submitted

A risk analysis of the device modifications was completed in accordance with Medtronic design control procedures. Verification and validation activities demonstrated that no new risks have been introduced to CD HORIZON® Spinal System by the addition of the subject lined rods, and that the addition of the subject lined rods does not create a new worst case for the overall CD HORIZON® Spinal System. The previously submitted testing for CD HORIZON® LEGACY™ 4.5 devices still applies.

XI. Conclusions Drawn from the Non-Clinical Tests

Verification and validation activities demonstrated that no new risks have been introduced to CD HORIZON® Spinal System by the addition of the subject lined rods, and that the addition of the subject lined rods does not create a new worst case for the overall CD HORIZON® Spinal System. Therefore, Medtronic believes the subject CD HORIZON® Spinal System, including the subject lined rods, to be substantially equivalent to legally marketed predicate devices, including the predicate CD HORIZON® Spinal System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 6, 2013

Medtronic Sofamor Danek USA, Incorporated
% Ms. Lauren E. Kamer
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K132111
Trade/Device Name: CD HORIZON® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP, KWQ
Dated: July 08, 2013
Received: July 09, 2013

Dear Ms. Kamer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K132111

Device Name: CD HORIZON® Spinal System

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Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132111